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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,991	01/23/2001	Gary K. Michelson	101.0101-00000	4198

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EXAMINER
PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/768,991	Applicant(s) MICHELSON, GARY K.	
	Examiner Pedro Philogene	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *applicant's amendment filed 01/30/2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-194* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-194* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14,17-34,37-52, 55-71,74-91,94-109,112-194 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser (6,432,106) in view of Bonuti (6,099,531) in view of Benzel et al (6,214,005).

With respect to claims 1,26,44,62,81,100, Fraser discloses a spinal implant (10) for insertion at least in part across at least the height of a disc space between adjacent vertebral bodies (52,54), the implant comprising opposed upper and lower surfaces (16,18) adapted to be placed toward and in contact each of the adjacent vertebral bodies, respectively from within the disc space; as best seen in figs. 7-9; a leading end (14) for insertion into the disc space and between the adjacent vertebral bodies; a trailing end (12) opposite the leading end, the trailing end having an exterior surface and an outer perimeter with an upper edge and a lower edge adapted to be oriented toward the adjacent vertebral bodies, respectively, as best seen in Figs. 1-9, the trailing end having a maximum height, as measured from the upper edge to the lower edge along the longitudinal axis of the human spine, the maximum height being adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space; as best seen in Fig: 9.

It is noted that Fraser did not teach of a plurality of bone screws receiving holes in the trailing end, as claimed by applicant. However, in a similar art, Bonutti evidences the use of a spacer having a plurality of bon e screws receiving holes in the trailing end to receive screws to fasten the spacer to the adjacent bones.

Therefore, given the teaching of Bonutti, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the screws holes of Bonutti in the fusion cage of Fraser to fasten the fusion cage to the vertebrae.

It is noted that the above combination of references did not teach of at least one of the hole adapted to only partially circumferentially surround a trailing end of a bone screw adapted to be received therein, at least one of the bone screw receiving holes passing through the exterior surface and one of the edges so as to permit the trailing end of the bone screw to protrude beyond the one of the edges; as claimed by applicant. However, in a similar art, Benzel et al evidence the use of a plurality of bone screw holes adapted to only partially circumferentially surround a trailing end of a bone screw adapted to be received therein and passing through an edge to permit the trailing of the bone screw to protrude beyond the end of the edge to block movement of the implant, and thereby its associated bone portions.

Therefore, given the teaching of Benzel et al. it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the partially circumferentially screw holes in the device Fraser/Bonutti to block movement of the implant, and thereby its associated vertebral portions.

As to claim 44, the trailing end being adapted to receive at least a portion of a bone screw passing therein that extends beyond the maximum height immediately adjacent thereto, is shown in FIGS.8-10 of Bonutti.

As to the perimeter having a gap, it is shown by Benzel et al. in Figs.7-10.

With respect to claims 2-14,17-25,26-34,37-43,45-52,55-61,63-71,74-80,82-91,94-99,101-109,112-148, the above combination of references discloses all the limitations as set forth in column 3-13, lines 1-67 of Benzel et al., and in column 2-4, lines 1-67 of Fraser.

Wit respect to claims 149-152, Bonutti disclose a device wherein at least one of the bone screw receiving holes passes through the upper edge, and at least one of the bone screw receiving holes passes through the lower edge of the trailing end; and as best seen in Figs. 7-11.

With respect to claims 153-194, Fraser discloses, column 3, lines 1-12, column 4, lines 5-10, in combination with the fusion cage, the use of insertion device, distraction and insertion device, the removal of the disk, the preparation of the implant area. Therefore, given the teaching of Fraser, the use of any given instrument in the preparation and implantation of a fusion cage is old and well known in the art; thus, using one or the other would be an obvious mechanical choice.

Claims 15,16,35,36,53,54,72,73,92,93,110,111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser (6,432,106) in view of Bonutti (6,099,531) in view of Benzel et al (6,214,005) Further in view of Lowery et al (5,364,399).

With respect to the above claims, it is noted that the above combination of references did not teach of a lock for retaining at least one or a plurality of bone screws within an implant, as claimed by applicant. However, in a similar art, Lowery et al evidence the use of a lock to engage the heads of the screws and provide a rigid fixation of the screws to the implant.

Therefore, given the teaching of Lowery et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a lock in the device of Fraser/Bonutti/Benzel to engage the heads of the screws and provide a rigid fixation of the screws to the implant.

Response to Amendment

Applicant's arguments filed 1/30/03 have been fully considered but they are not persuasive. See below.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is found in Benzel et al column 12, lines 51-55. Further, Bonutti teaches of a spacer having a plate with screw holes and a spacer with no plate but having screw holes in the trailing end.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

872-9302 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene
March 20, 2003

Pedro Philogene
PEDRO PHILOGENE
PRIMARY EXAMINER